Cromatest

LINEAR

SLE - Latex CE

CONTENTS			
REF	2430005	SLE-Latex	50 Tests
For *in vitro* diagnostic use only			

SLE-Latex

Determination of anti-DNP antibodies associated with Systemic Lupus Erythematosis

SLIDE TEST

PRINCIPLE

SLE-Latex Test is a rapid agglutination procedure, developed for the direct detection and the semi-quantitation on a slide of anti-deoxyribonucleoprotein antibodies (anti-DNP) in human serum.
The assay is performed by testing a suspension of latex particles coated with DNP against unknown serums. The presence or absence of a visible agglutination indicates the presence or absence of anti-DNP antibodies in the samples tested.

REAGENT COMPOSITION

R **SLE-Latex**. Suspension of polystyrene latex particles coated with DNP (calf thymus) in a buffered solution. Contains 0.95 g/L of sodium azide.

CONTROL + Human serum with anti-DNP activity. Contains 0.95 g/L of sodium azide.

CONTROL - Animal serum with negative anti-DNP activity. Contains 0.95 g/L of sodium azide.

Precautions: Components of human origin have been tested and found to be negative for the presence of antibodies anti-HIV 1+2 and anti-HCV, as well as for HBsAg. However, the controls should be handled cautiously as potentially infectious.

Warning: The reagents in this kit contain sodium azide. Do not allow to contact with skin or mucous membranes.

PACKAGING CONTENTS

REF 2430005, kit 50 tests.
1 vial SLE-Latex Reagent, 1x1 mL Positive control, 1x1 mL Negative control, 3 Test cards and 1x50 disposable stirrers.

STORAGE AND STABILITY

Store at 2-8ºC. Do not freeze. Frozen reagents could change the functionality of the test.
Reagent and Controls are stable until the expiry date stated on the label.
Reagent deterioration: particles and turbidity in controls indicate deterioration and should not be used. Bacterial contamination of reagents or specimens may cause false positive results.

REAGENT PREPARATION

Reagent and Controls are ready to use.

SAMPLES

Fresh, clear serum.
After the clear serum has been separated it may be stored at 2-8ºC for up to one week or longer periods at –20ºC.
Contaminated, lipemic, or hemolyzed samples should not be used.

MATERIAL REQUIRED

- Automatic pipettes.
- Saline solution (9 g/L NaCl, only for semi-quantitation procedure).
- Mechanical rotator, adjustable at 100 r.p.m.
- Laboratory alarm clock.

PROCEDURE

I. Qualitative Test

1. Bring the test reagents and samples to room temperature (Note 1).
2. Resuspend the Reagent vial gently. Aspirate dropper several times to obtain a thorough mixing.
3. Using an automatic pipette, place **1 drop (30 µL)** of the serum under test into one of the circles on the card. Dispense 1 drop of positive control and 1 drop of negative control into two additional circles.
4. Add 1 drop of SLE-Latex Reagent **(40 µL)** to each circle next to the sample to be tested.
5. Mix the contents of each circle with a disposable stirrer while spreading over the entire area enclosed by the ring. Use separate stirrers for each mixture.
6. Rotate the slide by means of a mechanical rotator (100 r.p.m.) for a period of **1 minute** (Note 2).
7. Observe immediately under a suitable light source for any degree of agglutination.

Reading
Nonreactive: Smooth suspension with no visible agglutination, as shown by negative control.

Reactive: Any degree of agglutination visible macroscopically.

II. Semi-quantitative Test

1. For each specimen to be tested place with an automatic pipette 30 µL of 9/L ClNa solution into each of the 6 circles of a card.
2. To circle one add 30 µL of specimen to the saline solution and, using the same tip, mix the saline solution with the sample by repeated aspiration and expulsion of the fluid and transfer 30 µL of the mixture to the saline solution in the second circle.
3. Continue with the 2-fold serial dilutions in a similar manner up to the sixth circle, and discard 30 µL from this circle. Final sample dilutions will be: 1:2, 1:4, 1:8, 1:16, 1:32, 1:64.
4. Test each dilution as described in steps 4-7 for the Qualitative Test.

Reading
Same as in Qualitative Test. The titer of the specimen is reported as the highest dilution that shows reactivity. The next higher dilution should be negative.

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QUALITY CONTROL

Positive and negative controls should be run daily following the steps outlined in the Qualitative Test, in order to check the optimal reactivity of the latex reagent.
The positive control should produce clear agglutination. If the expected result is not obtained, do not use the kit.

EXPECTED VALUES

A positive result indicates the level of anti-deoxyribonucleoprotein antibodies (DNP) is in the range commonly found in systemic lupus erythematosus (Note 3).

CLINICAL SIGNIFICANCE

Systemic lupus erythematosus (SLE) is a chronic inflammatory disease of unknown cause that affects multiple organ systems (articulations, skin, kidneys, central nervous system, heart, lungs). Immunologic abnormalities, especially the production of a number of antinuclear antibodies (ANA), are another prominent feature of this disease. The clinical course is marked by spontaneous remissions and relapses. Its multisystemic manifestations and the complications from the use of immunosuppressive agents make the diagnosis and management of this entity challenging.

The detection of ANA antibodies by laboratory methods include immnunofluorescence, LE Cells test and agglutination of coated latex particles. These antibodies anti-DNP are believed to cause the formation of the LE cell in vitro, with this unusual event occurring in 75-80% of those patients diagnosed as having SLE. Some patients having symptoms suggestive for SLE had been found negative with LE Cells Test. In these individuals, ANA antibodies may be demonstrated by methods other than the LE cell test, as latex agglutination or inmunofluorescence.

ANALYTICAL PERFORMANCE

Serum samples were tested with SLE-Latex from Linear: 29 had active SLE, 23 had clinically inactive SLE, 8 had connective tissue diseases and the remaining 95 were clinically normal or had some nonrelated diseases (anemia, infectious mononucleosis and rheumatic diseases). Results were compared with a standard LE Cell preparation assay and a fluorescent ANA method.

Samples from	*SLE-Latex Linear*	*LE Cell Preparat.*	*F-ANA Test*	*Total*
Active SLE	24 (83%)	25 (86%)	24 (83%)	29
Inactive SLE	4 (17.4%)	4 (17.4%)	16 (70%)	23
Connective tissue diseases	0 (0%)	1 (12.5%)	4 (50%)	8
Clinically normal / non related diseases	1 (1%)	1 (1%)	6 (6%)	95

LIMITATIONS OF THE PROCEDURE

- Serum from patients with scleroma, rheumatoid arthritis, dermatomyositis, and a variety of connective tissue diseases may elicit agglutination in the SLE test.
- As high levels of antibodies might affect the degree of agglutination, positive samples should be re-assayed using semi-quantitative procedure.
- Plasma samples should not be used because of the possibility of non-specific results.
- Drugs such as hydralazyne, isoniazid, procainamide and a number of anticonvulsant drugs can induce an SLE syndrome.

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NOTES

1. The sensitivity of the test may be reduced at low temperatures. The best results are achieved at 15-25ºC.
2. Samples giving indeterminate results may be retested increasing the rotation period to 2 minutes. Reaction times longer than 2 minutes might cause false positive results.
3. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

SOURCES OF ERROR

- Bacterial contamination of controls and specimens as well as freezing and thawing of the SLE-Latex Reagent may lead to false positive results.
- Traces of detergent in the test cards may give false positive results. Wash used cards first under tap water until all reactants are removed and then with distilled water. Allow to air dry, avoiding the use of organic solvents as they may impair the special finish on the slide.
- The SLE-Latex Reagent must not be used beyond its expiry date because a prolonged storage can affect the sensitivity of the reagent.

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QUALITY SYSTEM CERTIFIED
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